REMARKS

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24, 26, 28-30, 33, 34, 36-38 and 40-43 are pending in this application. Claims 24, 26, 37 and 40 are amended. Support for the amended claims can be found throughout the specification. No new matter is added.

It is submitted that the claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather, the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 24, 26-34, 36-38 and 40-43 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description and enablement. While Applicants disagree with the analysis set forth in the Office Action, claims 24 and 34 have been amended to recite that the polynucleotide response element (PRE) is an HIV Rev response element (RRE), in order to expedite prosecution. Applicants reserve the right to pursue the broader claims in continuing applications.

The rejection with respect to claim 37 is traversed. The claim does not require Rev-dependency, *i.e.*, Rev expressing cells; therefore, other equivalent means for achieving export of the RNA to the cytoplasm are applicable. As such, the claim requires "at least one retroviral polynucleotide response element (PRE) which is responsive to a nucleus-to-cytoplasm transport factor." The claim does not require a PRE that is responsive to Rev, *per se*. Rather, the claims only require a retroviral PRE that is responsive to a nucleus-to-cytoplasm transport factor. While lentiviral RRE is responsive to lentiviral Rev, which is a nucleus-to-cytoplasm transport factor, other retroviral PREs function the same as lentiviral RRE by being responsive to other Rev-like nucleus-to-cytoplasm transport factors. For example, the HTLV RxRE/Rex system is

functionally equivalent to the lentiviral Rev/RRE system. In addition, CTEs are capable of functionally replacing the lentiviral RRE, and thus eliminating Rev dependence, as CTE is responsive to a cellular factor that is considered to be functionally analogous to Rev. See Tabernero *et al.*, Journal of Virology, 70:5998-6011 (Sept. 1996), particularly the paragraph bridging columns 1 and 2 on page 5998. (This article was referenced in and submitted with the Amendment filed on September 29, 2003.) The fact that functional equivalents to the lentiviral Rev/RRE systems can be used in the instant invention is discussed, for example, in the first paragraph on page 7 of the application. Accordingly, Applicants were in possession of the claimed genus, retroviral polynucleotide response element (PRE), because numerous representatives of the genus are described in the specification and were known prior to the time of the invention.

Furthermore, the quantity of experimentation required to substitute Rev/RRE equivalents for HIV Rev/RRE is low. Direction and examples showing how to make and use such a system are present in the specification. The state of the art is such that several Rev/RRE analogous systems that perform equivalently to the HIV Rev/RRE system are known and described; and, the level of skill in the art is high. One of skill in the art would be able to use the instant specification and the knowledge available in the art at the time the application was filed to produce a retroviral vector particle comprising, *inter alia*, any known Rev/RRE system and any known functionally analogous system. It would be well within the means of the skilled artisan to determine and evaluate such a system that enhances export of RNA transcripts of the vector genome from the nucleus to the cytoplasm of an infected cell.

It is submitted that the claims meet the written description and enablement requirements of Section 112. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper are requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,

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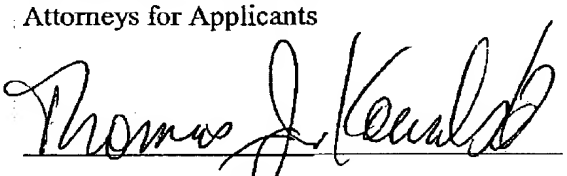
By: 

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